P/ NT COOPERATION TREAT

	From the INTERNATIONAL BUREAU
PCT	То:
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202
Date of mailing (day/month/year) 06 November 2000 (06.11.00)	ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/US00/01212	Applicant's or agent's file reference 3912.1PCT
International filing date (day/month/year)	Priority date (day/month/year)
19 January 2000 (19.01.00)	19 January 1999 (19.01.99)
Applicant DRAPER R Bruss et al.	
DRAPER, R., Bruce et al	
The designated Office is hereby notified of its election made X in the demand filed with the International Preliminary 18 August 2000 in a notice effecting later election filed with the Intern	Examining Authority on: 0 (18.08.00)
2. The election X was was was not was not made before the expiration of 19 months from the priority d Rule 32.2(b).	ate or, where Rule 32 applies, within the time limit under

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

C. Cupello

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35



From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: LAURENCE B. BOND
TRASK, BRITT & ROSSA
P.O. BOX 2550
SALT LAKE CITY, UTAH 84110

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing (day/month/year)

27 MAR 2001

Applicant's or agent's file reference

International application No.

3912.1PCT

IMPORTANT NOTIFICATION

International filing date (day/month/year)

PCT/US00/01212 19 JANUARY 2000

Priority Date (day/month/year)

19 JANUARY 1999

Applicant.

ROCKY MOUNTAIN RESEARCH, INC.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US

Commissioner of Patents and Trademarks Box PCT

Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

RICHARD A. MOLLER : Marciles

Telephone No. (703) 308-6715

Form PCT/IPEA/416 (July 1992) *



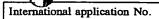
PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3912.1PCT	FOR FURTHER ACTION		ication of Transmittal of International Examination Report (Form PCT/IPEA/416)	
International application No.	International filing date (day/	month/year)	Priority date (day/month/year)	
PCT/US00/01212	19 JANUARY 2000		19 JANUARY 1999	
International Patent Classification (IPC) or national classification and IPC IPC(7): G01F 23/00 and US Cl.: 73/304C				
Applicant ROCKY MOUNTAIN RESEARCH, INC.				
 This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. This REPORT consists of a total of sheets. This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheets. 				
3. This report contains indications relating to the following items: I X Basis of the report II Priority III Non-establishment of report with regard to novelty, inventive step or industrial applicability IV Lack of unity of invention V X Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI Certain documents cited VII Certain defects in the international application VIII Certain observations on the international application				
Date of submission of the demand	Date	of completion	of this report	
18 AUGUST 2000	1	9 MARCH 20	01	
Name and mailing address of the IPEA/		orized officer	··· 、	
Commissioner of Patents and Tradem Box PCT Washington, D.C. 20231	rarks	ICHARD A.	MOLLER) La Callago	
Facsimile No. (703) 305-3230 Telephone No. (703) 308-6715				





PCT/US00/01212

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

I. Basis of the report	
With regard to the elements of the internal	ional application:*
X the international application as	• •
Alex Assert At	
pages1-12	an originally filed
pagesNONE	, as originally filed
Pugos	, filed with the demand , filed with the demand
pages	, fined with the letter of
X the claims:	
pages13-16	, as originally filed
pages NONE	, as amended (together with any statement) under Article 19
pages NONE	, filed with the demand
pagesNONE	, filed with the letter of
X the drawings:	
pages	, as originally filed
P ³ 6 ³	, filed with the letter of, filed with the demand
pages	, filed with the letter of
X the sequence listing part of the de	escription:
	, as originally filed
pages NONE	, filed with the demand
pages NONE	, filed with the letter of
the language of a translation fur the language of publication of the	which is: nished for the purposes of international search (under Rule 23.1(b)). ne international application (under Rule 48.3(b)). shed for the purposes of international preliminary examination (under Rules 55.2 and/
	amino acid sequence disclosed in the international application, the international out on the basis of the sequence listing:
contained in the international ap	plication in printed form.
filed together with the internation	nal application in computer readable form.
furnished subsequently to this A	uthority in written form.
=	uthority in computer readable form.
	ly furnished written sequence listing does not go beyond the disclosure in the
international application as filed h	as been furnished.
The statement that the information is been furnished.	recorded in computer readable form is identical to the writen sequence listing has
4 X The amendments have resulted in	n the cancellation of:
X the description, pages	NONE
v	NONE
the claims, Nos.	NONE
X the drawings, sheets/fig_	
	me of) the amendments had not been made, since they have been considered to go
* Replacement sheets which have been furnish	dicated in the Supplemental Box (Rule 70.2(c)).** ned to the receiving Office in response to an invitation under Article 14 are referred to the receiving of this report since they do not contain amendments (Rules 70.16).
•	mendments must be referred to under item 1 and annexed to this report.



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/01212

statement			
Novelty (N)	Claims	1-29	Y
• • •	Claims	NONE	N
Inventive Step (IS)	Claims	1-29	Y
• \ /	Claims	NONE	N
Industrial Applicability (IA)	Claims	1-29	Y
•	Claims	NONE	N
 NONE			
NONE			
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International application No. PCT/US00/01212

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IPC(7)	ASSIFICATION OF SUBJECT MATTER :G01F 23/00			
US CL :73/304C According to International Patent Classification (IPC) or to both national classification and IPC				
	CLDS SEARCHED			
	documentation searched (classification system follows	owed by classification symbols)		
U.S. :	73/304C			
Document NONE	ation searched other than minimum documentation to	o the extent that such documents are included	l in the fields searched	
ł	data base consulted during the international search	(name of data base and, where practicable	, search terms used)	
C. DO	CUMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where	appropriate, of the relevant passages	Relevant to claim No.	
X	US 5,135,485 A (COHEN et al) (figures 2, 6, 13, abstract, column 5, 50		1-29	
x	US 5,051,921 A (PAGLIONE) 24 S abstract, figures 1-8, column 5, lines	1-29		
x	US 5,005,407 A (KOON) 09 APR figures 1-3, column 3, lines 25-30, c	IL 1991, (09/04/91) abstract, column 4, lines 55-65.	1-29	
Furthe	r documents are listed in the continuation of Box	C. See patent family annex.		
A" docu	ial categories of cited documents: sment defining the general state of the art which is not considered to particular relevance	To later document published after the inte- date and not in conflict with the appli the principle or theory underlying the	cation but cited to understand	
E* carli	er document published on or after the international filing date	"X" document of particular relevance; the considered novel or cannot be consider		
cited	ment which may throw doubts on priority claim(s) or which is to establish the publication date of another citation or other ial reason (as specified)	"Y" document of particular relevance; the	•	
•	ment referring to an oral disclosure, use, exhibition or other	considered to involve an inventive combined with one or more other such being obvious to a person skilled in th	step when the document is documents, such combination	
	ment published prior to the international filing date but later than riority date claimed	"&" document member of the same patent	family	
Pate of the ac	ctual completion of the international search	Date of mailing of the international sear 05 MAY 2000	ch report	
Commissioner Box PCT	iling address of the ISA/US r of Patents and Trademarks	Authorized officer RICHARD A. MOLLER	ich)	
Washington, I	D.C. 20231 (703) 305-3230	Telephone No. (703) 308-6715	- /0	



INTERNATIONAL SEARCH REPORT



International application No. PCT/US00/01212

	PCT/US00/01212 •
B. FIELDS SEARCHED Electronic data bases consulted (Name of data base and where practical	ble terms used):
EAST search terms: transducer, sensor, fluid, level, electrodes, capacitive, pla containers, vessel	ates, capacitance,
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PENT COOPERATION TREATY

PCT

REC'D 30 MAR 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPOR

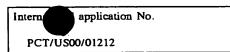
IPO	PCT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference	N	Co. Natification of Tourning of Learning		
3912.1PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)		
International application No.	International filing date (day/mo	onth/year) Priority date (day/month/year)		
PCT/US00/01212	19 JANUARY 2000	19 JANUARY 1999		
International Patent Classification (IPC) or national classification and IPC IPC(7): G01F 23/00 and US Cl.: 73/304C				
Applicant ROCKY MOUNTAIN RESEARCH, IN	NC.			
Examining Authority and is 2. This REPORT consists of a This report is also accompleen amended and are the	transmitted to the applicant act total of sheets. panied by ANNEXES, i.e., sheet e basis for this report and/or sheet ton 607 of the Administrative In	s of the description, claims and/or drawings which have ets containing rectifications made before this Authority.		
		ma:		
3. This report contains indications relating to the following items: I X Basis of the report II Priority III Non-establishment of report with regard to novelty, inventive step or industrial applicability IV Lack of unity of invention V X Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI Certain documents cited VII Certain defects in the international application VIII Certain observations on the international application				
Date of submission of the demand	Date of	of completion of this report		
18 AUGUST 2000	19	MARCH 2001		
Name and mailing address of the IPEA/	US Author	rized officer		
Commissioner of Patents and Tradem Box PCT	arks	00000		
Washington, D.C. 20231	ċ. RI	CHARD A. MOLLER)		
Facsimile No. (703) 305-3230 Telephone No. (703) 308-6715				





I. Basis of the	report		
1. With regard to the	e elements of the internation	nal application:*	
	tional application as or	••	
the descrip			
pages	1-12		, as originally filed
pages			, filed with the demand
pages	NONE	, filed with the lette	er of
X the claims	:		
pages			, as originally filed
pages			her with any statement) under Article 19
pages		filed with the letter of	, filed with the demand
pages	NONE	, filed with the letter of	
X the drawing	ngs:		
pages			, as originally filed
pages	NONE		, filed with the demand
pages	NONE	, filed with the letter	of
X the sequen	ce listing part of the des	crintion:	
nages	NONE		, as originally filed
pages	NONE		, filed with the demand
pages	NONE	, filed with the letter	of
the langua	ge of a translation furning ge of publication of the	shed for the purposes of internat	inguage which is: tional search (under Rule 23.1(b)). Rule 48.3(b)). preliminary examination (under Rules 55.2 and/
		mino acid sequence disclosed in t at on the basis of the sequence lis	he international application, the international ting:
contained:	in the international app	lication in printed form.	
filed toget	her with the internation	al application in computer reada	ble form.
furnished s	subsequently to this Au	thority in written form.	
furnished s	subsequently to this Au	thority in computer readable for	n.
The statem internations	ent that the subsequently all application as filed ha	furnished written sequence listing seen furnished.	g does not go beyond the disclosure in the
The statement been furnish		corded in computer readable form is	s identical to the writen sequence listing has
4. X The amen	dments have resulted in	the cancellation of:	
X the	description, pages	NONE	
X the	claims, Nos.	NONE	
		NONE	
5. This report	has been drawn as if (son	ne of) the amendments had not been	made, since they have been considered to go
•		licated in the Supplemental Box (Ru	
* Replacement shee in this report as and 70.17).	as which have been furnished or and are	ed to the receiving Office in response to e not annexed to this report since th	o an invitation under Article 14 are referred to ney do not contain amendments (Rules 70.16
**Any replacemen	t sheet containing such ar	nendments must be referred to unde	r item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Intern	l application No.	
PCT/U	\$00/01212	

statement			
Novelty (N)	Claims	1-29	YE
, , ,	Claims	NONE	NO
Inventive Step (IS)	Claims	1-29	YE
mvenave step (15)	Claims	NONE	NO
Industrial Applicability (IA)	Claims	1-29	YI
	Claims	NONE	NO
Claims 1-29 meet the criteria set out in PCT for detecting fluid in a container in which the areas of the electrodes are vertically and	e sensor compr horizontally of	ises first and second electrodes arrang	e such that a majority of
 NONE			
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From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
BOND, Laurence, B.
Trask, Britt & Rossa
P.O. Box 2550

Salt Lake City, UT 84110 ETATS-UNIS D'AMERIQUE RECEIVED

JUL 3 1 2000

Trask Britt

Date of mailing (day/month/year)

20 July 2000 (20.07.00)

Applicant's or agent's file reference 3912.1PCT

IMPORTANT NOTICE

International application No. PCT/US00/01212

international filing date (day/month/year) 19 January 2000 (19.01.00) Priority date (day/month/year)

19 January 1999 (19.01.99)

Applicant

ROCKY MOUNTAIN RESEARCH, INC. et al

 Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

 AU,JP,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

CA,EP

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

 Enclosed with this Notice is a copy of the international application as published by the International Bureau on 20 July 2000 (20.07.00) under No. WO 00/42395

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

J. Zahra

Telephone No. (41-22) 338.83.38





INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7:		(1	1) International Publication Number:	WO 00/42395
G01F 23/00	A1	(4	3) International Publication Date:	20 July 2000 (20.07.00)
(21) International Application Number: PCT/USc (22) International Filing Date: 19 January 2000 ((81) Designated States: AU, CA, JP, US CH, CY, DE, DK, ES, FI, FR, NL, PT, SE).	, European patent (AT, BE, GB, GR, IE, IT, LU, MC,
(30) Priority Data: 60/116,302 19 January 1999 (19.01.99)	τ	us	Published With international search report.	
(63) Related by Continuation (CON) or Continuation-in (CIP) to Earlier Application US Not furnish Filed on Not		-		
(71) Applicant (for all designated States except US): MOUNTAIN RESEARCH, INC. [US/US]; 825 N West, Suite #NE500, Salt Lake City, UT 84103 (U	North 3			
(72) Inventors; and (75) Inventors/Applicants (for US only): DRAPER, R [US/US]; 1672 Success Lane, Sandy, UT 8409 GRIFFITHS, Robert, W. [US/US]; 885 Monum Circle, Salt Lake City, UT (US).	92 (US	S).		
(74) Agents: BOND, Laurence, B. et al.; Trask, Britt & Ro Box 2550, Salt Lake City, UT 84110 (US).	ossa, P.0	О.		
(54) Title: METHOD AND APPARATUS FOR DETECT	TON C)F 4	A FILID LEVEL IN A CONTAINER	

(57) Abstract

A fluid level sensor is disclosed having first and second vertically and horizontally non-overlapping electrode plates for placing on a wall of a fluid container. Most preferably, the plates are also vertically spaced from each other. The capacitor plates are driven by a high frequency square wave. By forming non-overlapping plates and driving them using a high frequency, the level of a fluid within the container, particularly viscous fluid, is more accurately detected. Control and detection circuitry is also disclosed to trigger an alarm if the fluid level drops below a critical level within the container.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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EE	Estonia	LR	Liberia	SG	Singapore		

METHOD AND APPARATUS FOR DETECTION OF A FLUID LEVEL IN A CONTAINER

-1-

PRIORITY CLAIM

This application claims the benefit of the filing date of United States Provisional Patent Application Serial Number 60/116,302, filed January 19, 1999, for "METHOD AND APPARATUS FOR DETECTION OF A FLUID LEVEL IN A CONTAINER."

10 TECHNICAL FIELD

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The present invention relates generally to determining a level of a fluid in a container. More specifically, the invention relates to a method and apparatus for more accurately sensing when a relatively rapid egress of a viscous fluid, such as blood, reaches a level within the container. The invention is particularly useful in applications wherein a reduction in fluid level leaves a film of the fluid on an inner wall of the container.

BACKGROUND

Both rigid and flexible containers are used in many industries to hold and dispense fluids of various natures. Accordingly, fluid level sensors and corresponding circuitry to indicate the quantity of fluid within a container or when the fluid reaches a particular level within the container, such as with a gas tank of a car, are well known.

In the medical industry, both rigid and flexible containers are used with a variety of fluid level sensors. Sterile intra-venous ("i.v.") bags and bottles are commonly used in hospitals to dispense plasma, whole blood, replacement electrolytes, etc. These containers are usually labeled to indicate their contents and volumes. When using such containers, a frequently used procedure is to dispense a metered amount of fluid over a given period of time by unmonitored, gravity-fed, drip feeding. The containers themselves come in different sizes and shapes, and the fluids are administered to patients in widely varying flow rates which are often difficult to estimate exactly. Consequently, without directly monitoring the container throughout its use, it is often difficult to determine when all of the fluid within a container will have been dispensed.

PCT/US00/01212

It is detrimental to a patient to have the flow of an i.v. fluid come to a complete stop, unattended, because of complications which can occur from the stop of fluid flow. Complications may include the clogging of the needle due to blood clotting, usually requiring reinsertion of a new needle, or blood passing out of the patient into the tubing. The more frequently a needle is inserted and reinserted into a vein, the greater the risk for complications and infection.

-2-

WO 00/42395

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Solutions for medical fluid container monitoring range from complicated electronic, motor-driven, peristalic pump-type systems which exactly regulate the fluid flowing from the container to predict when it will run out, to relatively low cost sensors which produce an audible alarm when the fluid has reached a particular level within its container. U.S. Patent 3,641,543 to Rigby (Feb. 8, 1972) describes a probe-type fluid level sensor wherein two probes are placed within the fluid container to monitor the fluid level based upon the capacitance of the bottle/probes system. However, a common concern associated with probe-type fluid level sensors and other sensors which must be placed on the inside of the container involves the risk of introducing contamination into the fluid. For a hospital environment, particularly where fluids generally come in presterilized containers, introducing a probe into the fluid to determine its level is a great risk, and providing presterilized sensors already within the containers increases health care costs and requires hospitals to use common equipment for monitoring the sensors.

Sensors have also been developed for sensing fluid levels from the outside of a non-conductive container. Three-conductor sensors are shown in both U.S. Patents 3,939,360 to Jackson (Feb. 17, 1976) and 4,083,038 to Klebanoff (Apr. 4, 1978). For each of these sensor systems, three conductive strips are placed in a parallel, vertically and horizontally overlapping arrangement on the side of a rigid container. An associated audible alarm signals when a fluid level within the container has dropped below a level determined by the position of the sensor on the container. For the three-conductor sensor systems, the alarm is triggered by a difference in capacitance between a first and a second of the conductive strips, and the capacitance between the second and a third of the conductive strips.

-3-

U.S. Patent 5,135,485 to Cohen et al. (Aug. 4, 1992), the disclosure of which is hereby incorporated herein by reference, describes another capacitance-type fluid level sensing system having a fluid sensor comprising two conductive strips affixed to a flexible container in a parallel, vertically or horizontally overlapping relationship substantially coextensive with each other. Associated with the fluid sensor is a system of circuitry to produce an alarm signal when fluid in the container approaches a predetermined level determined by the position of the fluid sensor on the container and the settings of the control circuitry.

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The control circuitry disclosed in Cohen et al. applies a reference voltage to a first resistor/capacitor combination and to a first input of a first monostable multivibrator. The control circuitry also applies the output of the resistor/capacitor combination to a second resistor/capacitor combination and to a first input of a second monostable multivibrator, and an oscillating wave to a second input of each of the monostable multivibrators. At the start of each oscillator cycle, the monostable multivibrators are triggered and the outputs of the multivibrators monitored to determine whether the first input of each monostable multivibrator rises to a predetermined level before the multivibrators are triggered again. When the first inputs of both multivibrators rise fast enough that their signals exceed a predetermined level before a subsequent triggering, a signal is produced to indicate the fluid level is below a desired level. The flexible container, fluid and sensor act as the capacitor in the first resistor/capacitor combination, the response of which adjusts the rise time of the input signal to the first multivibrator as the fluid level in the flexible container changes. As the volume of liquid within the flexible container decreases, the rise time of the output of the second monostable multivibrator increases such that the amplitude of the input signal increases with a decrease of the fluid level until the alarm level is reached.

U.S. Reissued Patent 34,073 to Suzuki (Sep. 22, 1992), the disclosure of which is hereby incorporated herein by reference, describes a capacitance-type fluid level sensing system having two conductive strips affixed to a flexible container. Suzuki discloses both a horizontally overlapping, parallel configuration and a configuration wherein a second conductor is placed immediately opposite a first conductor on a

-4-

container such that they are in a parallel, vertically overlapping configuration, but not immediately adjacent to each other on a common surface.

Venous blood containers, which are made of a rigid or flexible resin, are employed in heart-lung bypass circuits used during open heat surgery. It is critical to monitor the fluid (blood) level in such containers in a manner which provides an accurate and timely signal as to when blood in the container has been reduced below a certain level. While capacitance-type level sensors have been employed in an attempt to measure such blood levels, the viscous nature of blood leaves a film on the interior walls of the container, giving a false level indication. This phenomenon may be exacerbated during the latter stages of emptying a flexible bag when the inner walls of the bag tend to sag together, trapping the blood film therebetween. It is, therefore, desirable to have an external fluid level sensor which overcomes the problems associated with accurately sensing the levels of viscous fluids in both rigid and flexible containers.

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DISCLOSURE OF INVENTION

The present invention addresses the problems of conventional capacitance-type fluid level sensing devices by providing a reliable, relatively simple, capacitance-type level sensor system which is substantially less susceptible to false level readings attributable to the presence of a residual film of viscous fluid, such as blood, on an inner wall of a container to which the level sensor of the invention is affixed.

The system of the invention includes a disposable sensor permanently or removably placed on or inside a wall of a flexible or rigid, electrically non-conductive container. The sensor comprises two electrodes formed of essentially two-dimensional plates of electrically conductive material deposited on a thin, insulative film backing. The conductive material and the entire sensor assembly may be made opaque, translucent or transparent, as desired or required for the intended application. Alternatively, the sensor plates may be formed directly on the material comprising the container wall.

Each of the two plates of the sensor acts as a plate for a capacitor, the fluid inside the container acting as the second plate for each capacitor and conducting the electric field between the capacitors. The container wall acts as a dielectric for the

capacitor. As the fluid level within the container changes, the capacitance changes slightly. This change in capacitance is detected by control circuitry which activates visual and auditory alarms if the capacitance drops below a predetermined level.

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The size of the sensor in terms of plate length and vertical as well as any horizontal separation of the plates may be optimized for the system frequency and container wall material and thickness, as well as the nature of the fluid, the level of which is to be monitored. The plates of the sensor are arranged with a vertical separation to allow detection of a rapid decrease of fluid level where a residual layer or film of fluid is left on the container walls. Horizontal separation of the plates may be adjusted depending upon the resistance attributable to the fluid film on the interior of the container wall. The sensor is most preferably configured so that the capacitor plates are arranged with a vertical separation so that an upper plate is completely exposed and the film is allowed to dissipate while the fluid is still lowering over a second, lower plate. The plates may also be horizontally separated by at least a small distance, or at least not overlap horizontally to maximize the film resistance between the sensors. The above-described sensor and control circuit configuration allows the level detection of blood and other conductive fluids that leave a conductive film left the container wall.

The system further includes a control box housing detection and control circuitry and is attached to the sensor with a connector and flexible cable. The connector may be a Zero Insertion Force (ZIF) connector as known in the art. If desired, the cable and connector may be made part of a sensor assembly, and disposable therewith. The control box incorporates both audio and visual alarms to indicate that the sensor is not connected to the control box as well as if the sensor does not detect the fluid (i.e., the fluid level is below the sensor).

As noted previously, many fluids, particularly those of substantial viscosity, leave thin conductive films on the container walls that may take seconds, or even minutes, to thin to a level where a conventional capacitor-type level sensor may detect the change. To be able to accurately detect rapidly-changing fluid levels in spite of the thin, conductive, fluid film left on the container walls, several things should happen. First, as noted above, it is desirable to drive the sensor capacitance with a high frequency of about 4 MHZ or greater. At lower frequencies, for example, 1 MHZ, a residual film of blood on a container wall may give a false level reading, indicating

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erroneously that the blood level within the container is at or higher than the level of the sensor. The thin conductive fluid film may be characterized as small capacitive electrodes extending through the resistive portion of the film. The film resistance and capacitances together act as a low pass filter. Therefore, increasing the frequency reduces the effect of the capacitance in the residual film adjacent the sensor.

The control box circuitry is configured to detect a change in capacitance of the sensor by applying a high frequency, preferably at least about 4 MHz, and most preferably at least about 8 MHz, square wave to a series resistor and capacitor network. The resistor is located in the control box and the capacitor network is provided by a combination of the cable capacitance and the sensor capacitance. This arrangement, and the driving signal, results in a substantially triangular wave output at the capacitor which is amplified and monitored for a small change in amplitude resulting from a change in the network capacitance due to a fluid level change within the container.

The frequency of the square wave input signal has been selected by experimentation to minimize capacitance detected attributable to a thin layer of fluid remaining on the side walls of the container as the fluid level lowers past the sensor. When the capacitance lowers due to the fluid level lowering past the sensor, a comparator detects the amplitude change and filters the detection noise and produces visual and audio alarms.

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BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is a diagram of a sensor system according to the present invention;

Figure 2 is a diagram of a fluid level sensor according to an embodiment of the present invention;

Figure 3 is a block diagram of an embodiment of the control circuitry of the present invention;

Figure 4 is a timing diagram relating to signals within the control circuitry of the present invention; and

Figures 5a-5c are diagrams of a sensor and fluid container wall according to embodiments of the present invention.

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BEST MODES FOR CARRYING OUT THE INVENTION

Figure 1 depicts a fluid level sensor system 2 according to an embodiment of the present invention including a fluid container 4, a fluid level sensor 6, and detection and control circuitry housed in a control box 8. The fluid container 4 may be any fluid container having an electrically non-conductive wall such as both the rigid- and flexible-walled fluid containers commonly used in medical applications for storing blood, saline solution, human waste, or other fluids or mixtures. The fluid level sensor 6 may be affixed to a side of the fluid container 4 by an adhesive such as a pressure sensitive adhesive or other medical grade adhesive well known to one of ordinary skill in the art. The fluid level sensor 6 may be affixed to an outside wall of the fluid container 4 by medical personnel or other operator just before use, or formed on or within the fluid container wall as part of a manufacturing process and sold as an integral unit with the fluid container 4.

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A conductive cable 10, such as a coaxial cable or other two signal cable, couples the fluid level sensor 6 to the detection and control circuitry within the control box 8 and may be formed as part of the fluid level sensor 6, as part of the detection and control circuitry, or as a separate part to couple to both the fluid level sensor 6 and the detection and control circuitry prior to use. Most preferably, the cable 10 is coupled to the fluid level sensor 6 through a Zero Insertion Force ("ZIF") connector as is known in the art.

As illustrated in Figure 1, the detection and control circuitry most preferably includes an external switches for controlling the level sensor system 2 between On 12 and Off 14 states. Although the switching devices 12 and 14 of Figure 1 are shown as separate switching devices, other switching devices known in the art, such as a single-pole-double-throw switch, may serve the same function of activating and deactivating the circuitry. The detection and control circuitry also includes external alarm indicators 16 and 18 to enable both a visual alarm 16 and an audible alarm 18 from within the control box 8. Additionally, the detection and control circuitry may include other control devices such as buttons to deactivate an audible alarm or reset a system, and other indicators such as a display to indicate a more precise fluid level.

Figure 2 is a diagram of an embodiment of the fluid level sensor 6 of the present invention comprising a thin electrically insulative film 20, a pair of conductive plates

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22 and 24, and conductive traces 26 and 28 extending from each of the conductive plates 22 and 24 to a terminal area 35 to facilitate easier coupling between the conductive plates 22 and 24 and the detection and control circuitry 36 (see Figure 3). The two conductive plates 22 and 24 of the fluid level sensor 6 are preferably vertically spaced and horizontally non-overlapping, or offset plates of conductive material such as gold, silver, copper, aluminum, or other non-metallic conductor. Most preferably, an opaque or transparent conductive material such as screened silver or gold, or indium tin oxide ("ITO") such as is commonly used in electronic displays, is used to form the conductive plates 22 and 24 so that the conductive plates do not block an operators view of the fluid within the container. The thin electrically insulative film 20 may be formed of any insulating material suitable as a dielectric for a capacitor. An example of a suitable film includes MylarTM. As required by a particular application, the conductive and non-conductive materials comprising the fluid level sensor 6 may be made opaque, translucent or transparent. A connector insertion point indicator 34 is also preferably applied to the insulative film 20 to indicate to the user when the terminal area 35, including the enlarged trace ends, has been fully inserted into a connector socket.

Although vertically or horizontally overlapping or non-offset plates will function as a sensor, to the extent the sensor plates overlap or are not offset, the rate at which the circuit detects rapidly lowering fluid levels is significantly decreased. This decrease in performance is experienced because the fluid film remaining on the container wall continues to conduct more through the overlapping area. Experimentation has shown the best results where there is little or substantially no overlapping because the signal must travel a longer path through the fluid film.

The two conductive plates 22 and 24 operate, in conjunction with the fluid within the fluid container 4 (see Figure 1), as two capacitors in series, each conductive plate 22 and 24 forming a capacitor with the fluid in the fluid container 4 using the fluid container wall as a dielectric. As the fluid level within the fluid container 4 changes, the conduction between the plates change, causing a difference in the detected capacitance of the plate/fluid system changes.

A difficulty experienced with systems using vertically or horizontally overlapping conductive plates is that as the fluid level within the container decreases,

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there may be residual fluid film left on the walls of the container. For highly viscous fluids such as blood, the residual fluid left on the walls of the container may take a few seconds or even a few minutes to flow off. For fluid level sensors employing horizontally or vertically overlapping or partially overlapping plates, detection of the fluid level within the fluid container is more delayed than with non-overlapping plates. The non-overlapping arrangement of the plates 22 and 24 assists in a more rapid and accurate determination of when the fluid level within the fluid container 4 has reached a critical range near the sensor level. Arranging the sensor plates 22 and 24 with a larger vertical 32 separation enables an easier detection of a rapid decrease of fluid level where a residual layer or film of fluid is left on the container walls. Arranging the sensor plates 22 and 24 with a larger horizontal 30 separation adjusts for the system resistance attributable to the fluid film on the interior of the container wall. The amount of separation placed between the conductive plates 22 and 24 is limited, however, by the fluid level range within which an indication is acceptable. For example, by increasing the vertical 32 separation between the conductive plates 22 and 24, the accuracy of the sensor indication becomes more resistant to the effects of a viscous film, but the range within which the indication may initiate also increases. For the conductive plate arrangement illustrated in Figure 2, vertical spacing 32 changes had a greater effect on sensor accuracy than did horizontal spacing 30 changes because the fluid flow level decreased along a vertical axis.

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The dimensions of the conductive plates 22 and 24 in terms of plate thickness, width and length, as well as their horizontal 30 and vertical 32 spacing from each other may be optimized for the system frequency, container wall material and thickness, as well as the nature of the fluid, positioning of the sensor and quantity of fluid to be monitored. The thickness and to a lesser extent, the material, of the container is largely determinative of the conductive area required. The vertical offset 32 of the plates 22 and 24, one plate above the second, encourages the fluid film over the upper plate to thin out as the fluid is lowering over the lower plate. The horizontal offset 30, if any, of the sensor plates 22 and 24 increases the resistance between the plates attributable to the residual film on the inside of the container wall. Relatively larger or longer electrode plates are more desirable for use with relatively rigid containers with their thicker walls, to increase the relatively lower capacitance associated therewith.

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Relatively smaller or shorter electrode plates appear to produce superior results on flexible-walled containers. It is believed that one of ordinary skill in the art is sufficiently familiar with capacitor-type fluid sensor design techniques to design a suitable fluid level sensor 6 given the characteristics of the particular system for which the fluid level sensor 6 will be used. The conductive plates 22 and 24 are each coupled to control circuitry 36 (Figure 3) through conductive paths 26 and 28 secured to the insulating film 20 and extending to a terminal area 35.

Figure 3 illustrates a block diagram of detection and control circuitry 36 according to an embodiment of the present invention. The detection and control circuitry 36 is configured to detect a change in the capacitance of the sensor by applying a high frequency signal at point A, preferably at least about a 4MHz, and most preferably at least about an 8 MHz, square wave 58 (see Figure 4) to a series resistor 40, coupled to a first of two terminals 42 for connection to a fluid level sensor 6 such as that illustrated in Figure 2. The second of the two terminals 42 may be connected to a reference voltage such as ground. From the combination of the R-C constant effects of the resistor 40, and the capacitance caused by the fluid level sensor and sensor cable attached to the two terminals 42, the signal at the junction of the resistor 40 and the first of the two terminals 42 approximates a triangular wave 60 (see Figure 4). The triangular wave signal 60 (Figure 4) is input into an amplifier 44, such as an operational amplifier to boost the signal. The boosted signal is then filtered by a reference filter 46 to give a relative amplitude of the signal. The boosted signal is also sent through a detector 48 to establish a DC reference voltage to act as a threshold for the sensor alarm. The outputs of both the reference filter 46 and the detector 48 are compared using a threshold comparator 50 to determine whether the filtered reference 46 output signal exceeds the DC reference voltage threshold. When the output of the detector 48 exceeds the DC reference voltage threshold, the threshold comparator 50 output signal at point C drops low, indicating to the alarm and indicator driver circuit 56 that an alarm should be initiated. Alarm and indicator driver circuitry 56 initiates the visual indicator alarm 54 and the auditory alarm 52 in response to the threshold comparator 50 output going low.

Figure 5a depicts a fluid container wall 64 having a fluid sensor 66 affixed to an external surface of the wall 64. The fluid sensor 66 includes a thin electrically

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insulative mounting structure 68, first and second electrodes 70 and a terminal area 72 to which control circuitry may be coupled. Figure 5b depicts a fluid sensor 74 wherein the fluid sensor electrodes 76 are placed within the fluid container wall 78. The fluid sensor electrodes 76 may be placed within the fluid container wall 78 by forming the electrodes 76 on a surface of, or affixing the electrodes 76 to a surface of, one of two flexible or rigid wall sheets 80, and then affixing the wall sheets 80 to each other. Conductors 82 from each of the electrodes 76 may extend between the wall sheets 80 to a container wall exit point and terminal area, or as shown in Figure 5c, may extend through one of the wall sheets 80 to an external surface of the container for coupling to control circuitry. Figure 5c illustrates a sensor 84 affixed to an internal surface of a fluid container wall 86. The sensor in the embodiment of Figure 5c includes a thin electrically insulative film 88 isolating sensor electrodes 90 from an internal volume of the fluid container. In this way, when the fluid container is filled with fluid, the electrodes are not shorted by the fluid. The thin electrically insulative film 88 acts as the dielectric for the sensor capacitor in this embodiment. Conductors 92 may extend through the container wall 86 immediately behind the electrically insulative film 88 to allow for coupling with control circuitry while minimizing the possibility of contamination with the internal volume of the fluid container. Alternatively, conductors may extend along an inside surface of the fluid container wall 86 and exit the container at another location.

While the system is preferably powered with a conventional nine volt battery, other power sources could be easily adapted.

Obviously, the fluid-level sensor shown and described with reference to Figure 2, though particularly useful for detecting a lowering level of viscous fluid within a container, will also function for a rising level of fluid. One of ordinary skill in the art will understand the minor circuit modifications required to enable the sensor to detect and alert to fluid rising to a predetermined level.

It should be noted that for many control circuits known in the art, temperature compensation relative to ambient temperature (≈ 22° C) may be necessary to ensure accurate level detection. Since the temperature of the environment in which the system of the invention is employed may vary significantly, particularly in less-developed regions of the world where operating rooms are not climate controlled, such

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temperature compensation is believed to be a significant feature of the system. It should also be noted that bloods with higher hematocrits (red blood cell percentages) are more viscous and thus more likely to fail to initiate a low fluid level signal if the electrode plates are not appropriately sized and spaced.

While the invention has been described in terms of a preferred embodiment, it will be understood and appreciated by those of ordinary skill in the art that it is not so limited. Many additions, deletions and modifications to the embodiment disclosed herein may be made without departing from the scope of the invention.

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CLAIMS

What is claimed is:

- 1. A sensor for detecting a fluid level in a container, the sensor comprising first and second electrodes arranged such that a majority of their areas are vertically and horizontally offset from each other.
- 2. The sensor of claim 1, wherein the first and second electrodes are arranged such that their areas are substantially vertically and horizontally offset from each other.

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- 3. The sensor of claim 1, wherein the first and second electrodes are arranged such that their areas are completely vertically and horizontally offset from each other.
- 15 4. The sensor of claim 1, wherein the first and second electrodes are vertically spaced from each other.
 - 5. The sensor of claim 1, wherein the electrodes comprise substantially two-dimensional plates.

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- 6. The sensor of claim 1, further comprising a conductor coupled to each of the first and second electrodes.
- 7. The sensor of claim 6, wherein the conductors coupled to each of the first and second electrodes are also coupled to control circuitry.
 - 8. The sensor of claim 7, wherein conductors coupled to each of the first and second electrodes are coupled to the control circuitry through a Zero Insertion Force connector.

- 9. The sensor of claim 1, further comprising control circuitry, the control circuitry configured to supply an oscillating signal to one of the first and second electrodes having a frequency greater than 1 MHZ.
- 5 10. The sensor of claim 9, wherein the control circuitry is configured to supply a signal at a frequency of at least about 4 MHZ.

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11. The sensor of claim 10, wherein the control circuitry is configured to supply a signal at a frequency of at least about 8 MHZ.

12. The sensor of claim 1, further comprising control circuitry configured to detect a change in a capacitance of the sensor.

- 13. The sensor of claim 1, further comprising at least one alarm responsive to an output signal of the sensor.
 - 14. The sensor of claim 1, wherein the electrodes are horizontally spaced.
- 15. The sensor of claim 1, wherein the first and second electrodes are isolated from a volume within the container.
 - 16. The sensor of claim 15, wherein the first and second electrodes are placed on a wall of the container.
- 25 17. The sensor of claim 16, further comprising a mounting structure to which the first and second electrodes are affixed.
 - 18. The sensor of claim 17, wherein the mounting structure is a thin electrically insulative film.
 - 19. The sensor of claim 18, wherein the thin electrically insulative film is Mylar.

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- 20. The sensor of claim 15, wherein the electrodes are placed within the wall of the container.
- A method for detecting a level of a fluid within a container, comprising:
 placing a capacitive structure including first and second electrodes arranged such that a majority of their areas are vertically and horizontally offset from each other on a wall of the container;

driving the capacitive structure at a frequency of more than about 1 MHZ and generating an output signal from the capacitive structure responsive thereto; adjusting a fluid level within the container; and detecting a change in the output signal responsive to the adjusting of the fluid level.

- 22. The method of claim 21, wherein placing a capacitive structure on a wall of the container comprises placing a capacitive structure within the wall of the container.
- 23. The method of claim 21, wherein driving the capacitive structure at a frequency of more than about 1 MHz further comprises driving the capacitive structure at a frequency of at least about 4 MHz.
- 24. The method of claim 21, wherein driving the capacitive structure at a frequency of more than about 1 MHz further comprises driving the capacitive structure at frequency of at least about 8 MHz.
- 25. The method of claim 21, wherein placing the capacitive structure on a wall of the container comprises forming the capacitive structure on a mounting structure and affixing the mounting structure to an exterior wall of the container with adhesive.
- 30 26. The method of claim 21, wherein placing the capacitive structure on a wall of the container comprises forming the capacitive structure on the wall.

- 27. The sensor of claim 21, further comprising determining whether the output signal exceeds a reference signal.
- 28. The method of claim 27, further comprising initiating at least one alarm 5 if the output signal exceeds a reference signal.
 - 29. The method of claim 28, wherein the at least one alarm is at least one of an audible alarm and a visual alarm.

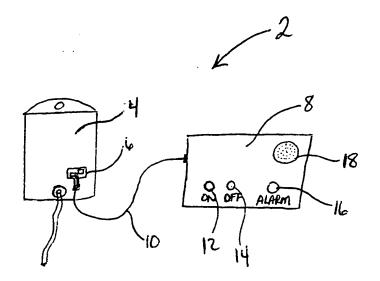
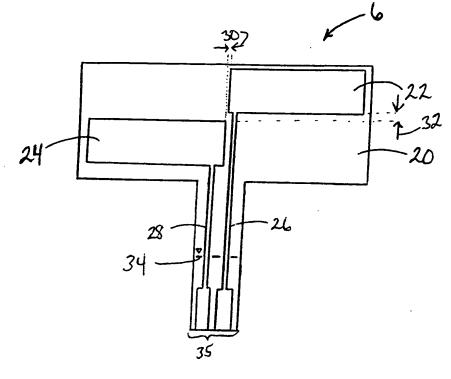


Figure 1



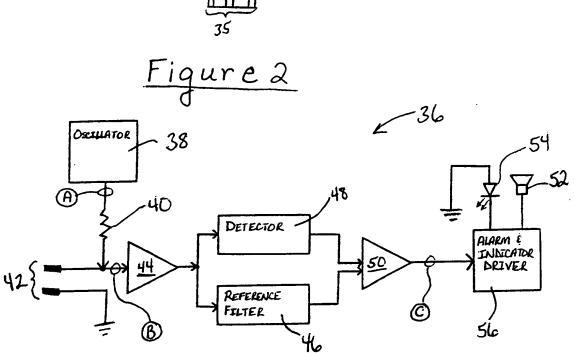
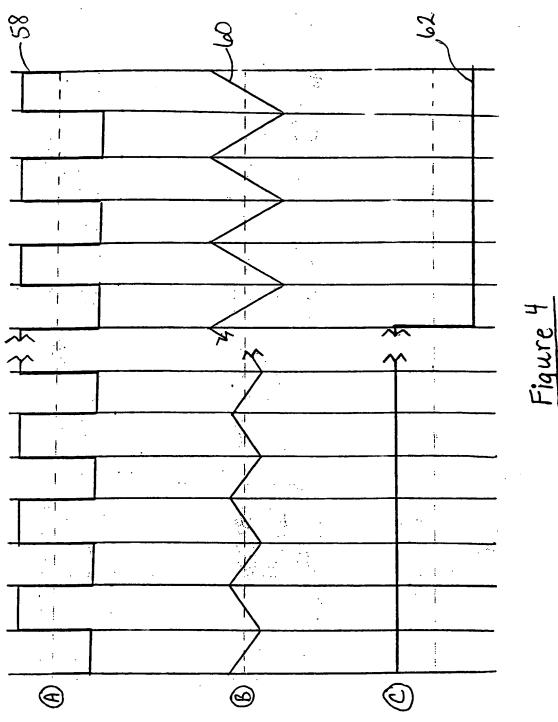
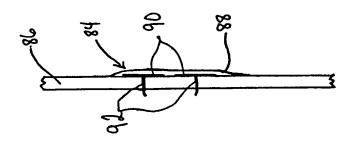


Figure 3







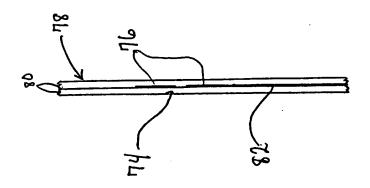


Figure Sb

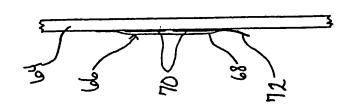


Figure Sa

A. CLA IPC(7) US CL	ASSIFICATION OF SUBJECT MATTER :G01F 23/00 :73/304C		
According	to International Patent Classification (IPC) or to both	h national classification and IPC	
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Minimum o	documentation searched (classification system follow	red by classification symbols)	
U.S. :	73/304C		
Documenta NONE	tion searched other than minimum documentation to t	he extent that such documents are included	l in the fields searched
Electronic	data base consulted during the international search (name of data base and, where practicable	, search terms used)
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C. DOC	CUMENTS CONSIDERED TO BE RELEVANT		
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	ument referring to an oral disclosure, use, exhibition or other	considered to involve an inventive combined with one or more other such being obvious to a person skilled in the	step when the document is documents, such combination
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Date of the a	actual completion of the international search 2000	Date of mailing of the international sear	rch report
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EAST earch terms: transduc	er, sensor, fluid, level, ele	ctrodes, capacitive, pla	tes, capacitance,	
ontainers, vessel				





SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number EP 00 90 5654

		DERED TO BE RELEVANT Indication, where appropriate,	Relevant	CLASSIFICATION OF THE
Category	of relevant pa		to daim	APPLICATION (Int.CI.7)
x	US 4 601 201 A (00 22 July 1986 (1986 * column 2, line 1	-07-22) 6 - line 53 *	1-7, 12-18	G01F23/26 G01F23/00
A	* column 3, line 4 figures 1,2 *	4 - column 4, line 54;	21	
A	US 5 142 909 A (BA 1 September 1992 (* column 5, line 3 figure 7 *		1-7, 12-18,21	
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	The supplementary search reposet of claims valid and available	ort has been based on the last earthe start of the search.		
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X: particularly relevant if taken alone
 Y: particularly relevant if combined with another document of the same category
 A: technological background
 O: non-written disclosure
 P: intermediate document

D: document cited in the application
L: document cited for other reasons

& : member of the same patent family, corresponding document





ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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